FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000629

EX0000629: RAW ORGANIC SINGLE WIDE CUT CORNERS	
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Product Modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decreasing the quantity of (b) (4) and (b) (4) (b) (4)
Attributes of Exemption Request	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Package Type	Booklet
Package Quantity	50 sheets
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2019.07.31 11:11:51 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.07.31 11:15:59 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000629: RAW ORGANIC SINGLE WIDE CUT CORNERS	
Product Name	RAW ORGANIC SINGLE WIDE SINGLE WINDOW
Package Type	Booklet
Package Quantity	50 sheets
Length	37 mm
Width	70 mm
Characterizing Flavor	None

The applicant manufactures the original tobacco product. The original tobacco product was previously found substantially equivalent by FDA under SE0015089.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 11, 2019, FDA received an Exemption Request (EX0000629) from BBK Tobacco & Foods LLP dba HBI International. On June 18, 2019, FDA issued an Acknowledgement letter to the applicant.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Decreasing the quantity of (b) (4) and (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Kaylene Charles on June 18, 2019. The review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000629 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0015089. Therefore, the original product[1] is eligible for modification under the Exemption Request pathway.

4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on July 15, 2019.

The review states that the new tobacco product has been modified by decreasing the quantities of the existing additives of (b) (4) and (b) (4) from the rolling paper. These substances are used in the manufacturing of the original tobacco product and are additives because the intended use may reasonably be expected to result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. This modification is the result of decreasing the existing additives of (b) (4) and (b) (4) due to the (b) (4) (b) (4). These modifications are not expected to influence HPHC yields of the new tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on July 3, 2019.

The environmental review found that the environmental assessment (EA) states that the EA is for a product quantity change for an SE Report. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Decreasing the quantity of (b) (4) and (b) (4)

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines an "additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I concur with the scientific review that (b) (4)

[1] Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

(b)(4) and (b) (4) are decreasing quantities of existing additives from the rolling paper. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco product to be marketed would be appropriate for protection of the public health. This modification is the result of decreasing the existing additives of (b) (4) and (b) (4) due to the remova (b) (4) . (b) (4) . These modifications are not expected to influence HPHC yields of the new product. Therefore, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, that an exemption for these modifications is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original tobacco product was previously found SE and in compliance with the FD&C Act by FDA under SE0015089.

FDA has examined the environmental effects of finding the new tobacco product exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an EX order.

An Advice/Information Request letter should be issued requesting the following information:

1. The environmental assessment (EA) submitted with your exemption request states that the EA is for a product quantity change substantial equivalence (SE) Report. However, your application is for FDA to issue an exemption from substantial equivalence reporting for a marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act for the introduction of your new roll-your-own rolling paper. Clarify in your EA that the requested action is for an exemption from SE reporting. This is important as the environmental impacts should be commensurate with the requested action.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order letter should be issued for the new tobacco product in EX0000629, as identified on the cover page of this review.